



Exhibit A (“Kim Declaration”) at ¶ 4.) In doing so, the IEPA found that Sterigenics’ emissions of ethylene oxide, a known human carcinogen, “create an imminent and substantial endangerment to the public health and welfare.” (*Id.* at Ex. 1 thereto (Seal Order) at ¶ 18.)

Plaintiff, does not satisfy any of the four factors for emergency injunctive relief, especially given that it has elected to bypass the state statutory procedures available to it. In terms of the factors, Plaintiff (1) is not likely to succeed on the merits because the state law provisions to remove the seal found in Section 34(d) of the Act satisfy due process, and the IEPA appropriately issued the Seal Order; (2) has not shown it has no adequate remedy at law; (3) has not shown irreparable harm; and (4) has not shown that the harm to the community from inhaling ethylene oxide outweighs any disruption to Sterigenics’ business.

### **Statutory Background**

Section 34 of the Act provides the IEPA with the authority to seal Plaintiff’s facility and sets forth a procedure to determine whether the seal should be removed:

- (b) In cases other than those identified in subsection (a) of this Section:

\* \* \*

- (2) At any other site or facility where the Agency finds that an imminent and substantial endangerment to the public health or welfare or the environment exists, the Agency may seal any equipment, vehicle, vessel, aircraft, or other facility contributing to the imminent and substantial endangerment.

\* \* \*

- (d) The owner or operator of any equipment, vehicle, vessel, aircraft or other facility sealed pursuant to this section is entitled to a hearing in accord with Section 32 of this Act to determine whether the seal should be removed; except that in such hearing at least one Board member shall be present, and those Board members present may render a final decision without regard to the requirements of paragraph (a) of Section 5 of this Act. The petitioner may also seek immediate injunctive relief.

415 ILCS 5/34 (2018).

### **Factual Background**

For more than thirty years, the facility now operated by Sterigenics in Willowbrook, Illinois, has been emitting ethylene oxide gas. (Dkt. 5, ¶ 11.) In December 2016, the United States Environmental Protection Agency’s (“USEPA”) Integrated Risk Information System (“IRIS”) program released a ten-year, peer-reviewed “Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide” (“2016 IRIS Evaluation”).<sup>1</sup> This evaluation concluded that based on the weight of the current scientific evidence, ethylene oxide is a known human carcinogen that is 30 times more potent at causing cancer than previously estimated.<sup>2</sup> Following this evaluation, the USEPA modeled and reported ethylene oxide emissions throughout the country and identified seven census tracts surrounding Sterigenics with a higher than acceptable cancer risk.<sup>3</sup> This modeled risk led the federal government to further model and study ambient ethylene oxide concentrations surrounding Sterigenics’ facility in Willowbrook.

In August 2018, the Agency for Toxic Substances and Disease Registry (“ATSDR”), a federal public health agency within the United States Department of Health and Human Services, concluded that based on measured and modeled ethylene oxide concentrations in ambient air as of May 2018, “an elevated cancer risk exists for residents and off-site workers in the Willowbrook community surrounding Sterigenics, and these elevated risks present a public

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<sup>1</sup> See *Integrated Risk Information System (IRIS): Ethylene oxide, History*, U.S. EPA, [https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance\\_nmbr=1025#tab-3](https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1025#tab-3).

<sup>2</sup> *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide*, INTEGRATED RISK INFORMATION SYSTEM (IRIS), at 1-7 (Dec. 2016), [https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/1025tr.pdf](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf).

<sup>3</sup> See 2014 National Air Toxics Assessment (“NATA”), U.S. EPA, <https://www.epa.gov/national-air-toxics-assessment/2014-nata-map>.

health hazard to these populations.”<sup>4</sup> Nearly six months later, ethylene oxide monitors around Sterigenics detected ethylene oxide in concentrations far above the May 2018 samples analyzed in the ATSDR report. Very recently, levels of ethylene oxide as high as 160 µg/m<sup>3</sup> (micrograms (one-millionth of a gram) per cubic meter of air) were detected near the Sterigenics facility. (Affidavit of Dyron Hamlin, a true and correct copy of which is attached hereto as Exhibit B (the “Hamlin Affidavit”), at ¶¶ 10, 11).<sup>5</sup> Nearly 20,000 people live within a mile of Sterigenics. (*People of the State of Illinois et al. v. Sterigenics U.S., LLC*, No. 2018-cv-08010 (N.D. Ill.), Dkt. 1, Attachment 1, ¶ 34.) The Village Hall and Police Department are across the street. (*Id.*)

The Illinois Constitution provides that: “the public policy of the State and the duty of each person is to provide and maintain a healthful environment for the benefit of this and future generations.” Ill. Const. 1970 art. XI, § 1. Importantly, it also provides that “each person has the right to a healthful environment.” *Id.* § 2. In fulfillment of the Constitutional requirements to provide a healthful environment and protect each person’s right to a healthful environment, in 1970, the General Assembly adopted the Act. 415 ILCS 5/1 *et seq.* Section 4(e) of the Act provides that the IEPA “shall have the duty to . . . take such summary enforcement action as is provided for by Section 34” of the Act. 415 ILCS 5/4(e) (2018). Section 34(b) of the Act provides the authority for the IEPA to issue an administrative order to seal a facility when “the Agency finds that an imminent and substantial endangerment to the public health or welfare or the environment exists.” 415 ILCS 5/34(b) (2018).

On February 15, 2019, the IEPA exercised this authority against the Sterigenics facility in Willowbrook due to the high levels of ethylene oxide being detected around its facility. In

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<sup>4</sup> See *Evaluation of Potential Health Impacts from Ethylene Oxide Emissions*, U.S. DEP’T OF HEALTH & HUM. SERVS. 1 (August 21, 2018).

<sup>5</sup> The 2016 IRIS Evaluation also sets forth a lifetime unit risk estimate including Age Dependent Factors of 5 cancers per 1,000 based on an exposure to 1 micrograms per cubic meter.

particular, the IEPA relied upon the ambient air sampling results obtained by the USEPA and the Village of Willowbrook, including sampling done in February. (Kim Declaration at ¶¶ 11, 12, 14.) The USEPA sampling data set forth double digit levels of ethylene oxide at offsite locations near the Sterigenics' facility for the first time. (*Id.*; Dkt. 6 at 20 fn. 20.) In addition, on February 14, 2019, the IEPA received a copy of the Village's February 5-8, 2019 sample results. (Kim Declaration at ¶ 14.) The measured airborne concentration of ethylene oxide at the Willowbrook Police Department – Outdoors location and the Willowbrook Village Hall-Outdoors location were 160 µg/m<sup>3</sup> and 38 µg/m<sup>3</sup>, respectively. (*Id.*) On February 19, 2019, IEPA received a copy of results from the Village's sampling conducted on February 11-14, 2019. (*Id.* at ¶ 19.) Per those results, the measured airborne concentration of ethylene oxide at the Willowbrook Police Department – Outdoors location was 320 µg/m<sup>3</sup>. (*See* Declaration of Dyron Hamlin, a true and correct copy of which is attached hereto as Exhibit C (the "Hamlin Declaration").)

### **Argument**

#### **I. The Applicable Standard**

In the Seventh Circuit, the standards for a temporary restraining order and a preliminary injunction "are functionally identical." *Crue v. Aiken*, 137 F. Supp. 2d 1076, 1082 (C.D. Ill. 2001). Injunctive relief "is an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion." *Goodman v. Ill. Dep't of Fin. & Prof. Reg.*, 430 F.3d 432, 437 (7th Cir. 2005) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (emphasis in original)).

To prevail under either theory, movants must demonstrate each of the following: "(1) they have a reasonable likelihood of success on the merits; (2) no adequate remedy at law exists; (3) they will suffer irreparable harm which, absent injunctive relief, outweighs the

irreparable harm the respondent will suffer if the injunction is granted; and (4) the injunction will not harm the public interest.” *Id.* If the movant has satisfied this standard, the court balances these factors against “any irreparable harm the nonmoving party would suffer if the court were to grant the requested relief.” *Girl Scouts of Manitou Council, Inc. v. Girl Scouts of U.S. of Am., Inc.*, 549 F.3d 1079, 1086 (7th Cir. 2008).

## **II. Plaintiff Is Not Entitled To Emergency Injunctive Relief.**

### **A. Plaintiff does not have a reasonable likelihood of success on the merits.**

#### **1. Count I of Plaintiff’s Complaint Fails to State a Complaint Upon Which Relief May be Granted, and No Federal Jurisdiction Exists Over Count II.**

Plaintiff is concurrently filing a Motion to Dismiss Plaintiff’s Complaint and hereby fully incorporates it by reference as though fully set forth herein. Plaintiff is not likely to succeed on the merits as to either of its two claims. As to Count I, there is no due process violation. Section 34(d) of the Act provides sufficient process options including proceeding before the Illinois Pollution Control Board (“IPCB”) or seeking immediate injunctive relief in state court. Plaintiff has elected not to avail itself of those statutory methods to attempt to lift the Seal Order. 415 ILCS 5/34(d) (2018). Sterigenics instead elected to bypass these remedies, however, and file this separate action in federal court, where it now argues that the State does not provide it with sufficient due process. This is nonsensical. Sterigenics’ failure to use the process afforded it in state court does not provide the basis for a federal due process claim, let alone an injunction against a state agency in federal court. A preference for litigating in federal court is not sufficient to confer subject matter jurisdiction. As to its second claim, contesting the IEPA’s issuance of the Seal Order, this is purely a state law claim. An Illinois agency issued the Seal Order pursuant to authority granted to it under a comprehensive set of environmental statutes

enacted by the Illinois General Assembly for the purpose of protecting human health and the environment. Moreover, the Eleventh Amendment bars Plaintiff's Claims. This Court lacks subject matter jurisdiction to hear this state law claim.

**1. Because the IEPA properly exercised its authority to protect human health and the environment, the Seal Order should not be removed.**

On February 15, 2019, the IEPA issued the Seal Order in the matter of *Commercial Sterilization Operations at 7775 South Quincy Street and 830 Midway Street, Willowbrook, DuPage County, Illinois* against Sterigenics U.S., LLC. (the "Seal Order"). (Kim Declaration at ¶ 4.) The IEPA performed its statutory duty in issuing the Seal Order pursuant to Section 4(e) of the Act. 415 ILCS 5/4(e) (IEPA "shall have the duty to . . . take such summary enforcement action as it provided for by Section 34"). Section 34(b) of the Act provides the authority for the IEPA to issue an administrative order to seal a facility when "the Agency finds that an imminent and substantial endangerment to the public health or welfare or the environment exists." 415 ILCS 5/34(b) (2018). The IEPA issued the Seal Order to protect human health from Sterigenics' emissions of ethylene oxide, which is a hazardous air pollutant under Section 112(b)(1) of the Clean Air Act, 42 U.S.C. 7412(b)(1).

In issuing the Seal Order, the IEPA properly relied upon the Public Health Consultation Letter that the ATSDR issued on August 21, 2018 (the "Consultation Letter"). (Kim Declaration at ¶ 7.) The ATSDR concluded in the Consultation Letter that:

- 1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *an elevated cancer risk exists* (emphasis in original) for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated cancer risks *present a public health hazard to these populations*. (emphasis in original).

(*Id.* at ¶ 8.) The ATSDR, in turn, relied upon the "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" that the USEPA's Integrated Risk Information System ("IRIS") program

released in December 2016 (“2016 IRIS Evaluation”). (*Id.* at ¶ 9.) The 2016 IRIS Evaluation, among other things:

- a. recharacterized ethylene oxide as from “probably carcinogenic to humans” to “carcinogenic to humans,” or a known human carcinogen;
- b. increased the lifetime inhalation cancer unit risk estimate for ethylene oxide about 30 times;
- c. recognized that an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers at sterilization operations using ethylene oxide, and
- d. recognized that there is sufficient evidence to establish a causal relationship between ethylene oxide exposure and breast cancer in women.

(*Id.*) The ATSDR used the highest [then-available] residential area and commercial area sampling results (2.1 µg/m<sup>3</sup> and 9.1 µg/m<sup>3</sup>, respectively) to reach its conclusion. (*Id.* at ¶ 10.)

The IEPA also relied upon (i) the USEPA’s results of sampling that it conducted in November and December 2018 (the “USEPA Results”), and (ii) the Village of Willowbrook’s results of sampling that it conducted in February 5-8, 2019 (the “February 5-8 Results”). (*Id.* at ¶ 11; *see also* Hamlin Affidavit.) The USEPA Results included multiple instances whereby the results were substantially higher than the highest applicable residential and commercial results that ATSDR utilized in reaching its conclusions that “an elevated cancer risk exists for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated cancer risks present a public health hazard to these populations.” (Kim Declaration at ¶ 12.) The higher results were particularly troubling given that in July 2018, Sterigenics completed a construction project to duct the emissions of ethylene oxide from the backvent valves of Sterigenics’ sterilization chambers to existing scrubbers, which Sterigenics told the IEPA would result in lowering ethylene oxide emissions from its Facility. (*Id.* at ¶ 13.)

The Village’s February 5-8 Results, which measured airborne concentration of ethylene oxide at the Willowbrook Police Department – Outdoors location and the Willowbrook Village



Hall-Outdoors location were 160  $\mu\text{g}/\text{m}^3$  and 38  $\mu\text{g}/\text{m}^3$ , respectively. (*Id.* at ¶ 14.) As a result of the Village's February 5-8 Results, the IEPA found that an imminent and substantial endangerment to public health existed, because (a) ethylene oxide is a known human carcinogen; (b) there was no significant source of ethylene oxide, other than Sterigenics, that could be contributing to the higher ethylene oxide concentrations; (c) the ATSDR had concluded, based upon 2.1  $\mu\text{g}/\text{m}^3$  for residential areas and 9.1  $\mu\text{g}/\text{m}^3$  that "an elevated cancer risk exists" and "[t]hese elevated cancer risks present a public health hazard" to the residents and workers exposed to the elevated airborne ethylene oxide concentrations); (d) the outdoor concentrations of ethylene oxide, a known human carcinogen, at the Willowbrook Police Department and Willowbrook Village Hall were substantially higher than the ATSDR and prior sampling results; and (e) the USEPA had identified 7 census tracts near Sterigenics' operations as having cancer risk scores greater than 1 in 10,000 (*i.e.*, an additional 1 incidence of cancer per 10,000 people). (*Id.* at ¶ 15.)

Section 34 of the Act, 415 ILCS 5/34 (2018), is the only provision of the Act, whereby the IEPA could fulfill its statutory duty and take immediate action to protect the public health. (*Id.* at ¶ 17.) The Seal Order should be rescinded only when measures are in place to prevent emissions of ethylene oxide that contribute to ambient levels of ethylene oxide which present a public health hazard to residents and off-site workers in the Willowbrook community. (*Id.* at ¶ 18.)

On February 19, 2019, the IEPA received a copy of results from the Village's sampling conducted on February 11-14, 2019, which measured airborne concentration of ethylene oxide at the Willowbrook Police Department – Outdoors location at 320  $\mu\text{g}/\text{m}^3$ . (*Id.* at ¶ 19; *see also* Hamlin Declaration.) Given the extremely high measured airborne concentration of ethylene

oxide at the Willowbrook Police Department – Outdoors location of 320  $\mu\text{g}/\text{m}^3$ , the Seal Order should not be rescinded. (Kim Declaration at ¶ 20.)

**2. An Imminent and Substantial Endangerment Existed, Warranting the Issuance of the Seal Order.**

There is no case law analyzing Section 34 of the Act. However, in *In City of Will ex. rel Masters v. Waste Mgmt. of Illinois, Inc.*, the Court held that “substantial danger to the environment” does not “mean only proven damage in the area affected.” Rather, “the term ‘danger’ imports a threatened ‘risk’ or ‘exposure’ to harm—necessarily an anticipated, rather than present injury.” 182 Ill. App. 3d 436, 443 (3d. Dist. 1989) (discussing basis for an injunction under Section 43(a) of the Act). In *People v. Conrail Corp.*, 251 Ill. App. 3d 550, 560 (4th Dist. 1993), the court found that “statutes which were enacted for the protection and the preservation of public health are to be given *extremely liberal construction* for the accomplishment and maximization of their beneficial objectives” and should frame a court’s interpretation of 34(b). (emphasis added). This is particularly true because the Court was analyzing Section 43(a) of the Act, 415 ILCS 5/43(a) (2018) (injunction where circumstances of substantial danger to the environment or to the public health of persons or to the welfare of persons), 34(b)’s counterpart. To this point, the IPCB and the USEPA have viewed Sections 43(a) and 34(b) as jointly satisfying the Clean Air Act’s requirement contained in section 110(a)(2)(G) that states possess emergency authority to administer the Act. 42 U.S.C. §7410(a)(2)(G); Approval and Promulgation of Air Quality Implementation Plans; Illinois; Infrastructure SIP Requirements for the 2008 Ozone, 2010 NO<sub>x</sub>, and 2010 SO<sub>2</sub> NAAQS, 79 Fed. Reg. 40,693-01 (July 14, 2014).

Like Section 34 of the Act, Section 303 of the federal Clean Air Act, 42 U.S.C. § 7603, allows the USEPA to issue an administrative order to cease operations that it deems to be

“presenting an imminent and substantial endangerment to public health or welfare, or the environment.” *Id.* USEPA guidance explains that Section 303 is a “precautionary provision, aimed at the avoidance of potential harm,” including but not limited to “chronic exposure to air pollution [that] causes endangerment by cumulative effect . . . .”<sup>6</sup> In upholding the USEPA’s view of the “endanger” standard in Section 211 of the Clean Air Act, 42 U.S.C. § 7521, the D.C. Circuit wrote that “regulatory action may be taken before the threatened harm occurs; indeed, the very existence of such precautionary legislation would seem to demand that regulatory action precede, and, optimally, prevent, the perceived threat.” *Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1, 13 (D.C. Cir. 1976).

Plaintiff’s generalized statement that the Seal Order “makes no attempt to show any sort of immediate [imminent] and substantial endangerment” ignores the full showing of such endangerment set forth therein. (Dkt. 5 at ¶ 5.) Based on the foregoing, the IEPA’s issuance of the Seal Order halting an “imminent and substantial endangerment to the public health or welfare” from Sterigenics’ carcinogenic emissions was warranted.

### **3. Sterigenics does not operate in full compliance with its operating permit.**

In its Complaint, Plaintiff alleges that “the Willowbrook facility is operating in full compliance with the operating permits issued by the IEPA, and all relevant and applicable regulations,” and that “[t]he Willowbrook facility is not in violation of any rules or regulations promulgated by the [USEPA] or IEPA.”<sup>7</sup> (Dkt. 1, ¶¶ 2, 14). This is false.

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<sup>6</sup> *Guidance on Use of Section 303 of the Clean Air Act*, U.S. EPA 2 (September 15, 1983), <https://www.epa.gov/enforcement/guidance-use-section-303-clean-air-act-caa>.

<sup>7</sup> Plaintiff assumes that the reference to rules or regulations promulgated by IEPA, as set forth in paragraph 14 of its Complaint is meant to refer to the IPCB. The IEPA is not the environmental rule making body in Illinois, the IPCB performs that role. 415 ILCS 5/5(b) (2018).

As set forth in its Complaint in *People of the State of Illinois et al. v. Sterigenics U.S., LLC*, No. 2018-cv-08010 (N.D. Ill.), (Dkt 1, Ex. 1), the State alleges Sterigenics is operating in violation of Section 9(a) of the Act and Section 201.141 of the IPCB Regulations, based on its having caused, threatened or allowed air pollution in Illinois. The Plaintiff removed the State of Illinois' Complaint to federal court, even though the Complaint sets forth only state law causes of action, where supplemental briefing is ongoing before Judge Lee. Moreover, Paragraph 18 of the Seal Order provide that Sterigenics' "emissions are continuing to contribute to ambient levels of ethylene oxide in the atmosphere. This impact creates an imminent and substantial endangerment to the public health or welfare." (Kim Declaration at ¶ 4, Ex. 1, Seal Order at ¶ 18.) Section 9(a) of the Act is an applicable Clean Air Act requirement as defined by Section 39.5.1 of the Act and therefore violations of Section 9(a) of the Act are also violations of the CAAPP permit, which provides at section 2.1:

"Prohibitions," provides:

It shall be unlawful for any person to violate any terms or conditions of this permit issued under Section 39.5 of the Act, to operate the CAAPP source except in compliance with this permit issued by the IEPA under Section 39.5 of the Act or to violate any other applicable requirements. All terms and conditions of this permit issued under Section 39.5 of the Act are enforceable by USEPA and citizens under the Clean Air Act, except those, if any, that are specifically designated as not being federally enforceable in this permit pursuant to Section 39.5(7)(m) of the Act.

(June 8, 2015, Clean Air Act Permit Program Permit No. No. 95120085.) It is apparent that the Defendants do not share the view that Sterigenics is in full compliance with its CAAPP permit or state environmental laws and regulations.

In sum, the Seal Order clearly and fully establishes that an imminent and substantial endangerment to public health and welfare exists due to the emission of ethylene oxide, a known human carcinogen into the environment surrounding Sterigenics' Willowbrook facility. The Seal

Order sets forth that the ATSDR found a public health hazard exists within that community when levels of ethylene oxide in the ambient offsite air were at 2.1  $\mu\text{g}/\text{m}^3$  and 9.1  $\mu\text{g}/\text{m}^3$  in residential and commercial areas, respectively. (Kim Declaration at ¶¶ 8-10.) The Seal Order further sets forth that sampling from November 2018, through February 2019 has found ethylene oxide levels even higher than those reviewed by ATSDR (*id.* at ¶¶ 11, 12, 14), even after Sterigenics began controlling previously uncontrolled source emissions of ethylene oxide installed after the May 2018 USEPA air sampling had occurred. (*Id.* at ¶ 13.) Plaintiff's generalized statement that the Seal Order "makes no attempt to show any sort of immediate [imminent] and substantial endangerment" ignores the full showing of such endangerment set forth therein.

**B. An Adequate Remedy At Law Exists.**

Plaintiff addresses this factor in conclusory fashion contending that it "lacks an adequate remedy at law if the Seal Order (which has [allegedly] already harmed Sterigenics, its employees and its customers) is not immediately enjoined." (Dkt. 6 at 24.) Further, Plaintiff claims that a shut-down would cause immediate "financial harm to Sterigenics and their customers." (*Id.*) However, financial harm is compensable with money damages, which is an adequate remedy at law. Therefore, this Court should deny Plaintiff's Motion.

**C. Plaintiff's Requested Injunction Has Not Caused Sterigenics Irreparable Harm, But Would Cause Irreparable Harm to The Public Interest.**

The third and fourth factors under *Goodman*, 430 F.3d at 437, whereby the (3) movant "will suffer irreparable harm which, absent injunctive relief, outweighs the irreparable harm the respondent will suffer if the injunction is granted; and (4) the injunction will not harm the public interest" are intertwined, because here, the IEPA is representing the public's interest. The increased risk to people in the community, and in particular to children, of getting cancer from Sterigenics' release of ethylene oxide, outweighs any monetary harm to Sterigenics or

“disruption” to the medical supply chain that may occur while customers find other alternatives and/or Sterigenics addresses the releases from its facility.

Sterigenics states that it is common for hospitals to keep a 30-day supply of sterilized medical equipment. (*See* Dkt. 6, Ex. C at ¶ 4.) Contrary to Sterigenics’ declarations, a period of time is available for its customers to find alternatives, especially since Sterigenics also states that its facility represents only 4% of the national ethylene oxide capacity. (*See* Dkt. 6, Ex. C at ¶ 6.) That leaves 96% of ethylene oxide capacity as alternatives, in addition to other types of available sterilization methods that are available.

Furthermore, Plaintiff’s affidavits are insufficient to carry its burden because the declarations do not demonstrate that a disruption will occur, nor do the declarations show whether any specific suppliers or end-user hospitals will be impacted. They also do not show the extent, if any, that hospitals will be impacted, and do not account for alternative suppliers, or alternative sterilization methods. The “threat of irreparable injury necessary to justify a TRO “must be ‘real,’ ‘substantial,’ and ‘immediate,’ not speculative or conjectural.” *Right Field Rooftops, LLC v. Chicago Baseball Holdings, LLC*, 80 F. Supp. 3d 829, 836 (N.D. Ill. 2015). The Plaintiff has not met that burden here.

The D.C. Circuit weighed competing public interest arguments in *Nat’l Ass’n of Farmworkers Organizations v. Marshall*, 628 F.2d 604 (D.C. Cir. 1980). The competing public interests the Court reviewed were: the health risks posed to children from picking produce that exposes them to pesticides and chemicals versus the potential economic impact to the produce growers, and by extension consumers of produce, if young children were no longer allowed to work the fields. The Court found protection of children’s health outweighed the economic burden to the growers and consumers. *Id.* at 616. Similarly, protection of the health of people in

the community, especially children, from the potential adverse health effects of breathing ethylene oxide, certainly outweighs any potential short-term disruption in the medical supply industry.

In short, the Seal Order protects the public interest by protecting men, women and children from the increased risk of cancer. Issuing a TRO or an injunction to lift the Seal Order would not. Accordingly, neither a TRO, nor a preliminary injunction is warranted.

### **Conclusion**

Plaintiff has failed to satisfy its burden of establishing each of the required elements for the granting of a TRO or preliminary injunction. Therefore, Defendant respectfully requests that the Court deny Plaintiff's Motion.

Respectfully Submitted,  
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